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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

LANDSMAN, R

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/626,616

Applicant(s)

YU, LEI

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-47, 65-74 and 76-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-47, 65-70, 72-74, 76-80 and 82 is/are rejected.
- 7) ☒ Claim(s) 71 and 81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence Comparisons A-F.

DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 4/30/01, has been entered into the record.
- B. Supplemental Amendment C, filed 4/30/01, has been entered into the record.
- C. Amendment B, filed 4/11/01, has been entered into the record.
- D. Claims 44-47 and 65-83 were pending in the application. Claim 75 was canceled. Therefore, claims 44-47 and 65-74 and 76-83 are pending. However, claim 44, as amended, now includes numerous distinct protein sequences and is, therefore, subject to restriction.
- E. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Information Disclosure Statement

- A. Reference C30 has been lined through since it is not in proper format for a citation. The author and date of publication of the references need to be included. The references on the search report listed as reference C30 on the Form Pto-1449 should be listed as separate citations and resubmitted.

Withdrawn Claim Objections

1. Brief Description of the Drawings

- A. The objection to the Brief Description of Drawings is withdrawn since Applicants have amended this section of the specification to refer to the individual parts of the drawings.
- B. The objection to claim 72 has been withdrawn since Applicants have amended the claim to recite "the candidate substance."

Withdrawn Claim Rejections

1. Claim Rejections - 35 USC § 112, first paragraph – lack of written description

A. The rejection of claims 65-70, 73, 74, 76-80 and 82 under 35 USC 112, first paragraph, is withdrawn since Applicants have provided a written description of fragments of at least 35 contiguous nucleotides of SEQ ID NO:7.

2. Claim Rejections - 35 USC § 112, first paragraph

A. The rejection of claims 44-47 under 35 USC 112, first paragraph, is withdrawn since Applicants have identified various portions of the receptor family which have biological activity.

2. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 44-47 under 35 USC 112, second paragraph has been withdrawn since Applicants have identified mu opioid receptors by SEQ ID NO.

B. The rejection of claim 73 (newly renumbered claim 72) under 35 USC 112, second paragraph has been withdrawn in view of Applicants' amendments to the claims.

3. Claim Rejections - 35 USC § 102

A. All rejections under 35 USC 102 have been withdrawn since neither Hawkins et al. nor Kennedy et al. teach the recited SEQ ID NOs.

Maintained Claim Rejections

1. Claim Rejections - 35 USC § 112, first paragraph – lack of written description

A. Claims 44-47 and 65-82 remain rejected under 35 USC 112, first paragraph, for the reasons of record on page 4 of the Office Action dated 12/06/00 since these claims still recite “interact with.” Applicants argue that the definition provided in the specification and as recited on page 16 of the response dated 4/11/01 makes this claim definite. However, the definition recites the phrase “other intramolecular interactions” which itself is not adequately described in the specification.

2. Claim Rejections - 35 USC § 112, second paragraph

A. Claim 44 remains rejected under 35 USC 112, second paragraph for the reasons already of record on page 7 of the Office Action dated 12/06/00. Applicants argue that the definition provided in the specification and as recited on page 16 of the response dated 4/11/01 makes this claim definite. However, the definition recites the phrase “other intramolecular interactions” which itself is vague. This could include screening for ligands which indirectly affect the claimed receptors by interacting at other receptors besides those of the present invention.

New Claim Objections

- A. Claims 71 and 81 are objected to since they depend from rejected base claims.
- B. Claim 72 is objected to since the syntax could be improved by reciting the word “the” after part (ii). Also, the second “(ii)” should be amended to recite “(iii)”.

New Claim Rejections

1. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al. (FEBS Letters 327:311-314, 1993; reference C20 on the IDS). The claims recite a process for screening a candidate substance for its ability to interact with a receptor of SEQ ID NO:2 by determining its binding affinity. Fukuda et al. teach a protein which is 100% identical to SEQ ID NO:2 (Sequence Comparison A). Fukuda et al. also teach a method of determining the binding of ligands to the expressed receptor (Figure 2 and Table I).

B. Claims 65-70, 72-74 and 76-80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (FEBS Letters 338:217-222, 1994; reference C35 on the IDS). The claims recite a process for screening a candidate substance for its ability to interact with a receptor comprising at least from 35 to 100 nucleotides of SEQ ID NO:7. Wang et al. teach a recombinant opioid receptor which is at least 100 nucleotides in length and which comprises guanine 389 (Sequence Comparisons B and C). Wang et al. also teach methods of determining the ability of ligands to interact with this receptor (Figure 2).

C. Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Mol. Pharmacol. 44, 8-12, 1993; reference C19 in the IDS). The claims recite a process for screening a candidate substance for its ability to interact with a receptor of SEQ ID NO:2 and 4 by determining its binding affinity. Chen et al. teach nucleic acids which encode proteins which are 100% identical to SEQ

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ID NO:2 and 4 (Sequence Comparisons E and F). Chen et al. also teach methods of determining the ability of ligands to interact with this receptor ("Materials and Methods").

2. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al. (FEBS Letters 343:42-46, 1994) in view of Fukuda et al. (FEBS Letters 327:311-314, 1993; reference C20 on the IDS). The claims recite a process for screening a candidate substance for its ability to interact with a receptor of SEQ ID NO:2 by determining its binding affinity. Fukuda et al. teach a protein which is 100% identical to SEQ ID NO:17 (Sequence Comparison D). Fukuda et al. do not teach a method of determining the binding of ligands to the expressed receptor. However, Fukuda et al. (reference ^{C20}~~C30~~) do teach a method of determining the binding of ligands to the expressed receptor (Figure 2 and Table I).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Fukuda et al. (FEBS 327) et al. by substituting a cDNA in the polycloning region of the vector with the polynucleotide (cDNA) of Fukuda et al. (FEBS 343) for the purpose of transfecting a host cell as taught by Fukuda et al. ("Materials and Methods 2.2") in order to express the protein encoded by the introduced DNA in a host cell to perform ligand binding and functional assays. There would have been a reasonable expectation of success for a person of ordinary skill in the art to make this invention since these techniques are widely used in the art and are highly successful. The present invention, therefore, is *prima facie* obvious over the above references in the absence of evidence to the contrary.

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Conclusion

Claims 71 and 81 would be allowable if rewritten in independent format including all the limitations of the base claim.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 16, 2001

Gary L. Kunz
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